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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

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DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,751

Applicant(s)

HUNTER ET AL.

Examiner

David J Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-45, 49 and 56-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-45, 57 and 58 is/are rejected.
- 7) ☒ Claim(s) 49, 56 and 59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

- [1]** Claims 43-45, 49, and 56-59 are pending in the application.
- [2]** Applicant's amendment to claims 43-45, 49, and 56-58 in Paper No. 11, filed June 06, 2003, is acknowledged.
- [3]** Receipt of references 3-6 as cited in the information disclosure statement of Paper No. 6 is acknowledged. A copy of the information disclosure statement acknowledging consideration of these references is attached to the instant Office action.
- [4]** Applicants' arguments filed in Paper No. 11 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [5]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Oath/Declaration

- [6]** The objection to the declaration as set forth in item 5 of the Office action of Paper No. 10 is maintained for the reasons of record. Applicant requests the submission of a supplemental declaration be deferred until the deficiency can be corrected.

Claim Rejections - 35 USC § 112, Second Paragraph

- [7]** The examiner's comment regarding the definiteness of the term "PfspI₁₅₅" was *not* a rejection, but was instead a statement to clarify the record that there is no ambiguity in the meaning of the term "PfspI₁₅₅". Applicant's affirm the examiner's interpretation of the term "PfspI₁₅₅" at page 4 of Paper No. 11, i.e., the term "PfspI₁₅₅" means SEQ ID NO:62 as defined in the specification at pages 24 and 94.

Claim Rejections - 35 USC § 112, First Paragraph

[8] The written description rejection of claims 43-45, 57, and 58 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a previous Office action (see item 9 of Paper No. 10). Applicant argues (beginning at the bottom of page 4 of Paper No. 11) only proteins comprising SEQ ID NO:62 and fragments thereof are being claimed. Applicant argues the examiner improperly does not give the recited sequence any patentable weight. Applicant argues SEQ ID NO:62 is a full-length protein with the defined function of being a flea allergen and therefore there is allegedly little variation among proteins comprising SEQ ID NO:62 since they all share SEQ ID NO:62 as a common feature. Applicant argues claim 43 has been amended to recite a functional limitation for fragments of SEQ ID NO:62, i.e., binding an IgE antibody having specificity for PfspI₁₅₅ (i.e., SEQ ID NO:62). Applicant argues there is little variation among the claimed fragments because they are all a portion of SEQ ID NO:62 and all have a common function. Applicant's arguments are not found persuasive. It is noted that the claims as presented in the amendment of Paper No. 9 are *not* limited to SEQ ID NO:62 or fragments thereof. Instead, claim 43 (as presented in the amendment of Paper No. 9) encompasses *all* proteins comprising a fragment of SEQ ID NO:62 - even the smallest fragment of SEQ ID NO:62, i.e., a single amino acid. Applicant discloses only nine representative species of the claimed genus of proteins in the specification, irrespective of whether eight of the nine representative species are withdrawn as non-elected inventions. As previously stated, these nine proteins species fail to represent the entire genus of claimed proteins. Claim 43 as presented in the instant amendment of Paper No. 11 also fails to adequately describe the claimed genus of proteins. Claim 43 (claims 44, 45, 57, and 58 dependent therefrom) is drawn to (in relevant part) a genus of flea saliva proteins comprising a fragment of SEQ ID NO:62, wherein the fragment binds an IgE antibody having specificity for PfspI₁₅₅. While neither the specification nor the claims indicate what number of amino acids of SEQ ID NO:62 constitute a fragment that would bind an IgE antibody, Harlow et al. ("Antibodies, A Laboratory Manual" page 76, Cold Spring Harbor Laboratory, 1998) teach that a peptide of as few as six amino acids can bind to an antibody. While an IgE antibody may bind an epitope of as

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few as six amino acids of PfspI₁₅₅, the antibody is not limited to binding PfspI₁₅₅ and can bind any protein comprising this epitope in *any* other protein having *any* function. Therefore, the genus of proteins of claim 43 encompasses *all* flea saliva proteins comprising a fragment of SEQ ID NO:62 that binds an IgE antibody having specificity for PfspI₁₅₅. Contrary to applicant's assertion, the claimed genus of proteins comprising a fragment of SEQ ID NO:62 that binds an IgE antibody having specificity for PfspI₁₅₅ encompasses species that are *widely* variant in both structure AND function, including (but not limited to) non-functional polypeptides and polypeptides having function other than that of SEQ ID NO:62. In this case, the specification discloses only a single representative species of the genus of claimed proteins, i.e., SEQ ID NO:62. The specification fails to describe any additional representative species of the claimed genus. While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus". As such, the disclosure of the single representative species of SEQ ID NO:62 is insufficient to be representative of the attributes and features of *all* species encompassed by the claimed genus of proteins. Given the lack of description of a representative number of proteins, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[9] The scope of enablement rejection of claims 43-45, 57, and 58 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a previous Office action (see item 10 of Paper No. 10). Applicant argues (beginning at the bottom of page 5 of Paper No. 11) the amended claims refer only to proteins comprising SEQ ID NO:62 or fragments thereof; the claims do not extend beyond sequences related to SEQ ID NO:62; and the claims do not encompass all proteins or *C. felis* proteins. Applicant argues fragments of SEQ ID NO:62 are not highly variant because a fragment is simply a portion of the full-length sequence and the examiner's comment regarding the use of hybridization and PCR to isolate nucleic acid sequences would

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seem to be incorrect as a skilled artisan can easily produce or identify fragments of a given sequence using such methods. Applicant argues the amended claims recite fragments that are required for biological function that is correlated with their utility. Applicant argues methods to determine binding of an antibody to a protein or peptide are well known and are also described in the specification. Applicant's arguments are not found persuasive. It is noted that the claims are not so limited to SEQ ID NO:62 or fragments thereof. Instead, the claims are so broad as to encompass *all* flea saliva proteins comprising a fragment of SEQ ID NO:62, wherein the fragment binds an IgE antibody having specificity for PfspI₁₅₅. As stated above, while neither the specification nor the claims indicate what number of amino acids of SEQ ID NO:62 constitute a fragment that would bind an IgE antibody, Harlow et al. ("Antibodies, A Laboratory Manual" page 76, Cold Spring Harbor Laboratory, 1998) teach that a peptide of as few as six amino acids can bind to an antibody. While an IgE antibody may bind an epitope of as few as six amino acids of PfspI₁₅₅, the antibody is not limited to binding PfspI₁₅₅ and can bind any protein having this epitope in any other flea saliva protein having any function. Thus, the claims encompass a *broad* scope of flea saliva proteins that would require undue experimentation for a skilled artisan to make and/or use the entire scope of the claimed invention. The Factors most relevant to the instant rejection were explained in detail in a previous Office action and are still relevant to the instant claims (see pages 5 and 6 of Paper No. 10), particularly those statements that address guidance for making the entire scope of claimed polypeptides by, e.g., PCR or hybridization.

Thus, it is the examiner's position that applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

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Claim Objection(s)

[10] Claims 49, 56, and 59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

[11] Status of the claims:


- Claims 43-45, 49, and 56-59 are pending
- Claims 43-45, 57, and 58 are rejected.
- Claims 49, 56, and 59 are objected to.
- No claim is in condition for allowance.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman
Patent Examiner
Art Unit 1652


REBECCA E. PROUTY
PRIMARY EXAMINER
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